K112109

DEC 2 2 2011

510(k) SUMMARY

ORTHO KINEMATICS, INC.

INTEGRAL SYSTEM COMPRISED OF THE KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) SOFTWARE AND ITS ACCESSORY DEVICE, THE MOTION NORMALIZER IMAGE™ PATIENT HANDLING AND DATA COLLECTION DEVICE

SUBMITTED BY

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DATE PREPARED

December 2, 2011

CLASSIFICATION NAME / PRODUCT CODE

System, Image Processing, Radiological / LLZ

DEVICE CLASS

Class II

REGULATION NUMBER

21 C.F.R. 892.2050

PROPRIETARY NAME

The integral system comprised of:
- the KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software, and its accessory device,
- the MOTION NORMALIZER™ patient handling and data collection device

PREDICATE DEVICE

Medical Metrics, Inc.'s KIMAX QMA Radiological Image Processing System (K022585)
Villa Sistemi Medicali, spa's Apollo (K050190)
Steris Corporation's Steris 5085 SRT (K090136)

INTENDED USE / INDICATIONS FOR USE

The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and

clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar spine images acquired with the assistance of the MOTION NORMALIZER™ patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar bending and data collection during imaging. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.

TECHNOLOGICAL CHARACTERISTICS / PRINCIPLES OF OPERATION

The subject device consists of the KINEGRAPH VMA™ software that analyzes images from the MOTION NORMALIZER™ on an Off-the-Shelf ("OTS") imaging workstation. The MOTION NORMALIZER patient handling and data collection device is an accessory device to the KINEGRAPH VMA™ software that is used to assist with subject lumbar bending and data collection while images are captured with standard fluoroscopes. The MOTION NORMALIZER is comprised of two powered, electromechanical patient handling devices connected to and controlled by a console-mounted OTS computer running custom software connected to various OTS hardware accessories. The subject system is able to capture and record fluoroscopic image data, as well as data from the patient handling devices, and to output this data into DICOM compatible digital image files for analysis using the KINEGRAPH VMA™ software.

PERFORMANCE DATA

The KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, have been designed and developed in accordance with FDA regulations, including validation and verification testing per FDA recognized standards. In addition, repeatability and accuracy testing was performed for the integral system. In all instances, the KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, functioned as intended.

SUBSTANTIAL EQUIVALENCE

The KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, has the same intended use and indications for use, technological characteristics, and principles of operation as the identified predicate devices. The minor technological differences between the KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, and the predicate devices raise no new issues of safety or effectiveness. Validation and verification data (including software validation) demonstrate that the subject device functions as intended, and performs functions substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ortho Kinematics, Inc.
% Mr. John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

DEC 2 2 2011

Re: K112109
Trade/Device Name: KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software and its accessory, the MOTION NORMALIZER™ patient handling and data collection device
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 5th, 2011
Received: December 5th, 2011

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112109

Device Name: **KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software and its accessory, the MOTION NORMALIZER™ patient handling and data collection device**

Indications for Use:

The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar spine images acquired with the assistance of the MOTION NORMALIZER™ patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar bending and data collection during imaging. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K112109